

Serial Number: 10/730,760

Filing Date: December 8, 2003

Title: TRENDED MEASUREMENT OF CARDIAC RESYNCHRONIZATION THERAPY

REMARKS

This responds to the Office Action dated December 7, 2005. No claims are amended, canceled or added. Thus, claims 1-60 remain pending in this application. Of these pending claims, claims 1-28 stand withdrawn from consideration.

§102/§103 Rejection of the Claims

Claims 29-30 were rejected under 35 U.S.C. § 102(b) as being anticipated by Schroepel et al. (U.S. Patent No. 5,749,900) or, in the alternative, under 35 U.S.C. § 103(a) as obvious over Schroepel et al. (U.S. Patent No. 5,749,900) in view of Stone et al. (U.S. Patent No. 6,280,409). Applicant respectfully traverses for at least the following reasons.

This rejection is confusing and inconsistent. On page 3, the Office Action states “Schroepel . . . meets the claimed limitation of wherein data trends include at least one CRT-related data parameter associated with time” at about line 14, and then states “Schroepel does not disclose data trends include at least one CRT-related data parameter associated with time” at about line 21.

Applicant is unable to find in Schroepel et al. or the combination of Schroepel et al. and Stone et al. a CRM device comprising, among other things, a communication circuit adapted to transmit the CRT-related data to an external device for presentation of data trends useful to assess the status of the prescribed CRT, wherein the data trends include at least one CRT-related data parameter associated with time, as recited in independent claim 29.

The present application discusses CRT and trended CRT data, and provides a number of examples of trended CRT data (page 14 line 16 to page 35 line 10). Stahmann et al. (US 6,480,742), which is relied upon in a rejection below, also discusses CRT (see, for example, col. 5 lines 51 ff.).

The rejection admits that Schroepel et al. does not show the claimed CRM. Schroepel et al. generally relates to heart rate variability analysis. Applicant has not found a reference to CRT. Applicant respectfully submits that the A-A, P-P, V-V or R-R intervals represent heart rate data used in a statistical analysis of heart rate variability, and do not represent trended CRT data. In paragraph 11, the rejection relies on the language “the peak detector measures the

timing of the peak amplitude, such as the A-A, P-P, V-V, or R-R interval of the heart signal” and asserts that these intervals are CRT-related data parameters associated with time. Applicant respectfully disagrees. A measured heart rate interval is not a CRT data parameter and does not represent trends of the CRT data parameter.

Stone et al. refers to a device that determines activity levels over a set of time periods (Abstract). The rejection asserts that FIGS. 4(a)-(c) discloses CRT-related data trends. However, FIGS. 4(a)-(c) plots activities per day against dates. Applicant respectfully submits that Stone et al. does not show, either in FIGS. 4(a)-(c) or elsewhere, data trends that include at least one CRT-related data parameter associated with time.

Thus, for at least these reasons, Applicant asserts independent claim 29 is in condition for allowance. Claim 30 depends on claim 29 and is in condition for allowance at least for the reasons provided with respect to claim 29. Applicant requests withdrawal of the rejection(s) and reconsideration and allowance of the claims.

§103 Rejection of the Claims

Claims 29-60 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Stahmann et al. (U.S. Patent No. 6,480,742) in view of Stone et al. (U.S. Patent No. 6,280,409). Applicant respectfully traverses for at least the following reasons.

Three basic criteria must be met to establish a *prima facie* case of obviousness. First, there must be some suggestion or motivation, either in the reference themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and not based on applicant’s disclosure. MPEP §2142, citing *In re Vaeck*, 947 F.2d 488 (Fed. Cir.1991).

Applicant respectfully submits that the combination does not show all of the language of the claims. MPEP 2143.03 states: “To establish *prima facie* obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art. *In re Royka*, 490 F.2d 981, 180 USPQ 580 (CCPA 1974). "All words in a claim must be considered in judging the

patentability of that claim against the prior art." *In re Wilson*, 424 F.2d 1382, 1385, 165 USPQ 494, 496 (CCPA 1970)." Applicant also submits that the rejection does not provide an objective rationale for combining the references. "The factual inquiry whether to combine references must be thorough and searching. It must be based on objective evidence of record. This precedent has been reinforced in myriad decisions and cannot be dispensed with." *In re Sang-Su Lee*, 277 F.3d 1338, 1343 (Fed. Cir. 2002). "[The] factual question of motivation to combine is material to patentability, and could not be resolved on subjective belief and unknown authority." *Lee*, at 1343-44. "The board cannot rely on conclusory statement when dealing with particular combinations of prior art and specific claims, but must set forth the rationale on which it relies." *Lee*, at 1343. Without such showings, there cannot be a reasonable expectation of success.

Applicant respectfully submits that the combination of Stahmann et al. and Stone et al. do not show a communication circuit adapted to transmit the CRT-related data to an external device for presentation of data trends useful to assess the status of the prescribed CRT, wherein the data trends include at least one CRT-related data parameter associated with time, as recited in independent claim 29. Applicant also submits that the combination of Stahmann et al. and Stone et al. do not show a system comprising, among other things, a CRM device and a programmer with a monitor, where at least one of the programmer and the CRM device is adapted to trend the CRT-related data, where the monitor is adapted to display information corresponding to the trended CRT-related data indicative of the status of the prescribed CRT, and where the trended CRT-related data include at least one CRT-related data parameter associated with time, as recited in independent claim 49. Additionally, Applicant submits that the combination of Stahmann et al. and Stone et al. do not show a system comprising, among other things, a CRM device and a programmer, where the programmer includes means for displaying information corresponding to the trended CRT-related data indicative of the status of the prescribed CRT, wherein the trended CRT-related data include at least one CRT-related data parameter associated with time, as recited in independent 54.

The rejection admits that Stahmann does not disclose data trends that include at least one CRT-related data parameter associated with time, nor means for displaying information including a graph and table of trended data.. The rejection asserts FIGS. 4(a)-(c) of Stone et al. discloses data trends that include at least one CRT-related data parameter associated with time.

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However, FIGS. 4(a)-(c) plots activities per day against dates. Applicant respectfully submits that Stone et al. does not show, either in FIGS. 4(a)-(c) or elsewhere, data trends that include at least one CRT-related data parameter associated with time. Stone et al. refers to a device that determines activity levels over a set of time periods (Abstract). Thus, neither Stahmann et al. nor Stone et al. disclose data trends that include at least one CRT-related data parameter associated with time.

In Stahmann et al., cardiac cycles are classified and counted for use in CRT. The combination of Stone with Stahmann provides a device that classifies and counts cardiac cycles for use in CRT (Stahmann) and determines activity levels over a set of time periods (Stone). In addition to the reason that the combination does not include all of the claimed subject matter, Applicant submits that the rejection fails to provide a proper suggestion or motivation to combine the references. The asserted motivation to combine is “to provide feedback to the clinician during use of therapy and to indicate the total amount of some algorithmically derived measure of activity over a given period of time, such as day or an hour and to display formatted data in a human readable form.” Applicant respectfully asserts that this reason does not provide objective evidence why one would want to measure activity over a given time period as part of a cardiac resynchronization therapy. Further, Applicant respectfully asserts that the reason does not provide a reason why one would be motivated to progress from measuring activity over a given period of time to provide CRT-related data trends.

Thus, for at least these reasons, Applicant asserts independent claims 29, 49 and 54 are in condition for allowance. Claims 30-48 depend on independent claim 29; claims 50-53 depend on claim 49; and claims 55-60 depend on claim 54. These dependent claims are in condition for allowance at least for the reasons provided with respect to their base claim.

Claim 53 was rejected under 35 U.S.C. § 103(a) as being unpatentable over Stahmann et al. (U.S. Patent No. 6,480,742) and Stone et al. (U.S. Patent No. 6,280,409) as applied to claim 49 above, and further in view of Schroeppel et al. (U.S. Patent No. 5,749,900). Applicant respectfully traverses. Claim 53 depends on claim 49. As provided above, the combination of Stahmann et al. and Stone et al. do not support the rejection of claim 49. The addition of Schroeppel et al. does not cure the deficiencies of the rejection to claim 49. Thus, claim 53 is in condition for allowance for at least the reasons provided with respect to claim 49.

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Finality of the Rejection

Applicant respectfully requests reconsideration of the finality of the rejection. The office action states that Applicant's amendment necessitated the new ground(s) of rejection in this Office Action. Applicant disagrees. As stated on page 18 of the previous Response, Applicant amended the claims to further clarify data trends/ trended data. The amendment did not change the intended scope of the claims. Neither the previous office action nor the present office action provided references that showed CRT-related data trends.

RESPONSE UNDER 37 CFR § 1.116 – EXPEDITED PROCEDURE

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CONCLUSION

Applicant respectfully submits that the claims are in condition for allowance and notification to that effect is earnestly requested. The Examiner is invited to telephone Applicant's attorney (612) 373-6960 to facilitate prosecution of this application.

If necessary, please charge any additional fees or credit overpayment to Deposit Account No. 19-0743.

Respectfully submitted,

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Date 2-7-06

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CERTIFICATE UNDER 37 CFR 1.8: The undersigned hereby certifies that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail, in an envelope addressed to: MS AF, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on this 7 day of February, 2006.

Name Paulo Sucky

Signature Paulo Sucky